

OCT - 9 1996

Heelbo, Inc.
ICU 911 Blazer Sleeved Jacket

Safety and Effectiveness Summary

1. Submitter's name, Address and Contact Person

Submitter

Heelbo, Inc.
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Contact Person

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Date Summary Prepared - August 14, 1996

2. Name of Device:

Heelbo ICU 911 Blazer Sleeved Jacket

3. Name of Predicate Device(s)

Heelbo ICU 911 Blazer Sleeved Jacket

4. Description of Device

The Heelbo ICU 911 Blazer Sleeved Jacket is a jacket-style safety vest. The Heelbo ICU 911 Blazer Sleeved Jacket is intended for use in the ICU (Intensive Care Unit), critical care situations as well as other area of the health care facility. The jacket is intended to help support and help prevent a patient from slumping or sliding forward while seated in a wheelchair or geri-chair. The Heelbo ICU 911 Blazer Sleeved Jacket is also intended to limit the patient's movement while lying on a bed or gurney to prevent the patient from falling out of bed or climbing over the side rails.

The jacket has short sleeves and straps on each side of the vest that can be tied together to ensure a comfortable fit. The jacket is constructed with Velcro® fasteners and a zipper in the back to ensure a secure fit as well as allowing for quick and easy release. Additional zippers are located on the back of the vest along each shoulder blade area of the device. These zippers are provided to allow the caregiver quick and easy access to vital monitoring support leads and IV lines. The jacket also has been designed with an extra deep neckline to accommodate tracheal tubes and arterial catheters.

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The jacket is secured to the bed or wheelchair with two straps that are attached to the bottom of the vest. Optional loops sewn to the shoulder area of the vest are provided in the event extra support is needed.

The ICU 911 Blazer Sleeved Jacket is available with a knotless system (quick disconnect option). This option allows the caregiver to quickly and easily disconnect the restraint from the chair or bed frame by eliminating time consuming untying of knots (a picture of the loop accessory is attached to this section).

The ICU 911 Blazer Sleeved Jacket is available in a poly/cotton blend or a polyester mesh material. Five sizes accommodate a wide range of patients. The ICU 911 Blazer Sleeved Jacket is made of durable machine washable materials and is color coded for easy size identification.

The following chart shows product availability:

ICU 911 Blazer Sleeved Jacket is Available in the following Sizes and Configurations

Series	Material	Size of Vest	Color
9417 9417K	Poly/Cotton blend	x-small	White
		small	Yellow
		medium	Blue
		large	Green
		x-large	Beige
9417B 9417BK	Polyester Mesh material	x-small	White bias on white breezewear
		small	Yellow bias on white breezewear
		medium	Blue bias on white breezewear
		large	Green bias on white breezewear
		x-large	Beige bias on white breezewear

5. Statement of Intended Use

The Heelbo ICU 911 Blazer Sleeved Jacket is intended to help support and help prevent a patient from slumping or sliding forward while seated in a wheelchair. The Heelbo ICU 911 Blazer Sleeved Jacket is also intended to limit the patient's movement while lying in bed to prevent the patient from falling out of bed or climbing over the side rails.

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6. Statement of Technological Characteristics of the Device

The jacket has short sleeves and straps on each side of the vest that can be tied together to ensure a comfortable fit. The jacket is constructed with Velcro® fasteners and a zipper in the back to ensure a secure fit as well as allowing for quick and easy release. Additional zippers are located on the back of the vest along each shoulder blade area of the device. These zippers are provided to allow the caregiver quick and easy access to vital monitoring support leads and IV lines. The jacket also has been designed with an extra deep neckline to accommodate tracheal tubes and arterial catheters.

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The subject devices are identical in intended use, design, materials, manufacturing process, physical and mechanical specifications and issues of safety and effectiveness to the devices prior to the submission of this notification. The only difference is that the product labeling has been revised to comply with the Agency's labeling requirements set forth in the draft "Guidance on the Content of Premarket Notification [501(k)] Submissions for Protective Restraints" dated December 1995.

7. Biocompatibility

The subject devices are identical in component materials to the predicate devices. The suppliers of the materials use in the fabrication of these devices have stated that there is a history of safe use of their materials in the clothing and garment industry. In addition, Heelbo, Inc., is not aware of any reports or complaints of skin irritation associated with these materials.

8. Conclusion

Based upon the information presented above it is concluded that the proposed Heelbo ICU 911 Blazer Sleeved Jacket is safe and effective for its intended use and is substantially equivalent to the predicate device.